

Evaluating the safety and efficacy of CCX354-C in subjects with rheumatoid arthritis partially responsive to methotrexate therapy

Submission date 30/11/2010	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 05/04/2011	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 25/10/2022	Condition category Musculoskeletal Diseases	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Prof Paul-Peter Tak

Contact details
Division of Clinical Immunology and Rheumatology
Academic Medical Center
Meibergreef 9
Amsterdam
Netherlands
1105 AZ

Additional identifiers

Clinical Trials Information System (CTIS)
2010-019964-36

ClinicalTrials.gov (NCT)
NCT01242917

Protocol serial number
CL004_354

Study information

Scientific Title

A randomised, double-blind, placebo-controlled, phase II study to evaluate the safety and efficacy of CCX354-C in subjects with rheumatoid arthritis partially responsive to methotrexate therapy

Acronym

CARAT-2

Study objectives

That CCX354-C will be safe and well tolerable by subjects with rheumatoid arthritis (RA) who had an inadequate response to methotrexate treatment.

Ethics approval required

Old ethics approval format

Ethics approval(s)

The Ethics Committee of the University Hospital and Medical School, Leige (Comite d'Ethique Hospitalo-Facultaire Universitaire de Leige [707]) approved on the 26th August 2010 (ref: 2010 /112)

Study design

Multicentre double blind randomised placebo controlled parallel group study

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Rheumatoid arthritis

Interventions

150 subjects with RA, partially responsive to methotrexate therapy will be randomised to one of the following treatment arms:

1. Placebo comparator: placebo tablet twice daily for 12 weeks + methotrexate
2. CCX354-C twice daily: 100 mg tablet twice daily for 12 weeks + methotrexate
3. CCX354-C once daily: 100 mg (2) tablets once daily for 12 weeks + methotrexate

To ensure patient safety, all patients will be followed for 28 days from the end of the intervention.

Intervention Type

Drug

Phase

Phase II

Drug/device/biological/vaccine name(s)

CCX354-C, methotrexate

Primary outcome(s)

Subject incidence of adverse events at 12 weeks

Key secondary outcome(s)

1. Disease Activity Score 28 using C-reactive protein (DAS28-CRP)
2. American College of Rheumatology (ACR) response criteria

All outcomes will be assessed at the end of the intervention period (12 weeks).

Completion date

30/08/2011

Eligibility

Key inclusion criteria

1. Adult subjects, with active RA, with at least 8 swollen joints, and 8 tender joints
2. Serum C-reactive protein (CRP) above upper limit of normal
3. Must have been on stable dose methotrexate for less than or equal to 8 weeks prior to randomisation
4. Willing and able to give written Informed Consent and to comply with the requirements of the study protocol
5. Female subjects of childbearing potential, and male subjects with partners of childbearing potential, may participate if adequate contraception is used during, and for at least the four weeks after, any administration of study medication

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Key exclusion criteria

1. Diagnosed with RA prior to 16 years of age
2. Have received sulfasalazine, azathioprine, 6-mercaptopurine, mycophenolate mofetil, tetracycline, cyclosporine, gold, tacrolimus, sirolimus, or other disease modifying anti-rheumatic drug (DMARD) within 8 weeks of randomisation
3. Use of infliximab, adalimumab, abatacept, certolizumab, golimumab, or tocilizumab within 8 weeks of randomisation
4. Use of leflunomide within 6 months of randomisation

5. Use of etanercept or anakinra within 4 weeks of randomisation
6. Use of a B-cell depleting agent such as rituximab or ocrelizumab, or cytotoxic agents, such as cyclophosphamide or chlorambucil, within one year of randomisation

Date of first enrolment

14/09/2010

Date of final enrolment

30/08/2011

Locations

Countries of recruitment

Belgium

Czech Republic

Germany

Hungary

Netherlands

Poland

Romania

Ukraine

Study participating centre

Division of Clinical Immunology and Rheumatology

Amsterdam

Netherlands

1105 AZ

Sponsor information

Organisation

ChemoCentryx, Inc. (USA)

ROR

<https://ror.org/04gp12571>

Funder(s)

Funder type

Industry

Funder Name

ChemoCentryx, Inc. (USA)

Results and Publications

Individual participant data (IPD) sharing plan

Not provided at time of registration

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/03/2013		Yes	No
Abstract results	conference abstract	08/11/2011		No	No
Abstract results	conference abstract	01/06/2013		No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes